BEFORE THE BOARD OF PHARMACY
DEPARTMENT OF LABOR AND INDUSTRY
STATE OF MONTANA

In the matter of the amendment of ARM 24.174.301, 24.174.501, 24.174.604, 24.174.711, 24.174.1411, and 24.174.2106, pertaining to definitions, foreign graduates, preceptor requirements, technician ratio and pharmacy security requirements, the adoption of new rule II, personnel, new rule III, absence of pharmacist, new rule IV, use of emergency drug kits, new rule V, drug distribution, new rule VI, pharmacist responsibility, new rule VII, sterile products, new rule VIII, return of medication from long term care facilities, and new rule IX, pharmacist meal/rest breaks, and the repeal of ARM 24.174.302, health care facility definition, 24.174.810, class I facility, 24.174.811, class II facility and 24.174.812, class III facility	)	NOTICE OF AMENDMENT, ADOPTION AND REPEAL

TO: All Concerned Persons

1. On July 11, 2002, the Board of Pharmacy published a notice of the proposed amendment, adoption and repeal of the above-stated rules at page 1868, 2002 Montana Administrative Register, Issue Number 13.

2. On August 15, 2002, the Board of Pharmacy published a notice of an additional public hearing and extension of the comment period concerning the proposed amendment, adoption and repeal of the above-stated rules at page 2159, 2002 Montana Administrative Register, Issue Number 15.

3. After considering the comments made, the Board has amended the following rules exactly as proposed:

24.174.604 PRECEPTOR REQUIREMENTS

24.174.2106 REGISTERED PHARMACIST CONTINUING EDUCATION - APPROVED PROGRAMS

4. After considering the comments made, the Board has amended the following rules as proposed but with the following changes, added material underlined, deleted material interlined:

24.174.301 DEFINTIONS (1) remains as proposed.

~~(2) "Class IV facility" means a family planning center under the administrative jurisdiction of the maternal and child health services bureau, department of public health and human services, and which has a Class IV facility pharmacy registered and licensed by the board.~~

(3) through (5) remain as proposed, but are re-numbered (2) through (4).

(6) and (7) remain the same, but are re-numbered (5) and (6).

~~(8)~~(7) "Drug order" means a written or electronic order issued by an authorized practitioner, or a verbal order promptly reduced to writing ~~and later signed by an authorized practitioner~~, for the compounding and dispensing of a drug or device to be administered to patients within the facility.

(9) remain as proposed, but is re-numbered (8).

(10) remains the same, but is re-numbered (9).

(11) and (12) remain as proposed, but are re-numbered (10) and (11).

~~(13)~~(12) "Facility" means an ~~ambulatory surgical facility~~ outpatient center for surgical services, a hospital and/or long term care facility, or a home infusion facility.

(14) and (15) remain as proposed, but are re-numbered (13) and (14).

~~(16)~~(15) "Home infusion facility" means a facility where parenteral solutions are compounded and distributed to outpatients for home infusion pursuant to a valid prescription or drug order.

~~(17)~~(16) "Institutional pharmacy" means that physical portion of an institutional facility where drugs, devices and other material used in the diagnosis and treatment of injury, illness, and disease are dispensed, compounded and distributed to other health care professionals for administration to patients within or outside the facility, and pharmaceutical care is provided~~; and which is registered with the Montana board of pharmacy~~.

(18) remains the same, but is re-numbered (17).

(19) and (20) remain as proposed, but are re-numbered (18) and (19).

(21) remains the same, but is re-numbered (20).

(22) remains as proposed, but is re-numbered (21).

(23) remains the same, but is re-numbered (22).

(24) and (25) remain as proposed, but are re-numbered (23) and (24).

(26) remains the same, but is re-numbered (25).

(27) remains as proposed, but is re-numbered (26).

AUTH: 37-7-201, MCA
IMP: 37-7-102, 37-7-201, 37-7-301, 37-7-406, MCA

24.174.501 EXAMINATION FOR LICENSURE AS A REGISTERED PHARMACIST (1) and (2) remain the same.

(3) ~~An~~ A successful interview ~~by~~ before the board of pharmacy or its designee, the test of English as a foreign language, test of spoken English and the foreign pharmacy graduate equivalency exam provided by the national association of boards of pharmacy will be required for pharmacy graduates from outside the 50 states, the District of Columbia or Puerto Rico, who seek certification of educational equivalency in order to sit for the North American pharmacist licensure examination. A scaled score of 75 or greater will be the passing score for this examination. A candidate who does not attain this score may retake the examination after a 91 day waiting period.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-302, MCA

24.174.711 RATIO OF PHARMACY TECHNICIANS TO SUPERVISING PHARMACISTS (1) through (7) remain as proposed.

(8) Nothing in this rule shall prevent a pharmacy from terminating a service plan upon written notification to the board.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-307, 37-7-308, 37-7-309, MCA

24.174.1411 SECURITY REQUIREMENTS (1) through (3) remain as proposed.

(4) The registrant shall notify law enforcement officials of any theft or loss of any dangerous drug promptly upon discovery of such theft or loss ~~and forward a copy of that agency's report to the board within 30 days~~.

AUTH: 50-32-103, MCA
IMP: 50-32-106, MCA

5. After consideration of the comments, the Board has decided not to adopt proposed NEW RULE I.

6. After consideration of the comments, the Board has adopted the following rule exactly as proposed:

NEW RULE VIII (ARM 24.174.1141) RETURN OF MEDICATION FROM LONG TERM CARE FACILITIES -- DONATED DRUG PROGRAM

7. After consideration of the comments, the Board has adopted the following new rules as proposed but with the following changes, added material underlined, deleted material interlined:

NEW RULE II (ARM 24.174.1101) PERSONNEL (1) Each institutional pharmacy must be directed by a pharmacist-in-charge who is licensed to engage in the practice of pharmacy

in the state of Montana and who is responsible for the storage, compounding, repackaging, dispensing and distribution of drugs within the facility. Depending upon the needs of the facility, pharmacy services may be provided on a full or part-time basis, with a mechanism for emergency service provided at all times. Contractual providers of pharmacy services shall meet the same requirements as pharmacies located within the institution.

(2) remains as proposed.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-307, MCA

NEW RULE III (ARM 24.174.1107) ABSENCE OF PHARMACIST IN INSTITUTIONAL SETTINGS (1) During times that an institutional pharmacy does not have a pharmacist in attendance, arrangements must be made in advance by the pharmacist-in-charge for provision of drugs to the medical staff and other authorized personnel by use of night cabinets, floor stock and, in emergency circumstances, by access to the pharmacy. ~~A pharmacist must be available by phone for consultation during all absences.~~ A mechanism for providers and nursing to obtain pharmacy consultation must be available at all times in accordance with ARM 24.174.1101.

(2) through (3)(e) remain as proposed.

(4) A complete verification audit of all orders and activity concerning the night cabinet must be conducted by the pharmacist-in-charge or the designee of that pharmacist within ~~24~~ 48 hours of the drugs having been removed from the night cabinet.

(5) Whenever any drug is not available from floor stock or night cabinets, and that drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, the drug may be obtained from the pharmacy by ~~a supervisory~~ an authorized registered nurse or licensed practical nurse in accordance with established policies and procedures. The responsible nurse shall be designated by the appropriate committee of the institutional facility.

(a) Removal of any drug from the pharmacy by an authorized nurse must be recorded on a suitable form left in the pharmacy showing the following information:

(i) and (ii) remain as proposed.

(iii) the name, strength~~,~~ ~~and~~ quantity and NDC number of drug removed;

(iv) the date and time the drug was removed; ~~and~~

(v) the signature of the nurse removing the drug~~.~~; and

(vi) documentation of pharmacy review.

~~(b) The form shall be sequestered in the pharmacy with the container from which the drug was removed, and a copy of the original drug order.~~

(6) A copy of the original drug order with the NDC number or other identifying code of the drug(s) provided may be faxed to the pharmacist. A patient profile containing the patient's name, location, allergies, current medication

regimen and relevant laboratory values must be ~~prospectively~~ reviewed.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

NEW RULE IV (ARM 24.174.1114) USE OF EMERGENCY DRUG KITS IN CERTAIN INSTITUTIONAL FACILITIES (1) and (1)(a) remain as proposed.

(b) the supplying pharmacist and the ~~staff physician~~ designated practitioner or appropriate committee of the institutional facility shall jointly determine the identity and quantity of drugs to be included in the kit;

(c) through (2) remain as proposed.

(3) The supplying pharmacist shall be notified of any entry into the kit ~~within 24 hours of its occurrence~~. The supplying pharmacist shall have a mechanism defined in policy to restock and reseal the kit within a reasonable time so as to prevent risk of harm to patients.

(4) and (5) remain as proposed.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

NEW RULE V (ARM 24.174.1111) DRUG DISTRIBUTION AND CONTROL IN AN INSTITUTIONAL FACILITY (1) The pharmacist-in-charge shall establish written policies and procedures for the safe and efficient distribution of drugs and provision of pharmaceutical care, including the mechanism by which ~~prospective~~ drug review will be accomplished and documented. A current copy of such procedures must be on hand for inspection by the board of pharmacy.

(2) and (3) remain the same.

(4) Investigational drugs must be stored in and dispensed from the pharmacy only pursuant to written policies and procedures. Complete information regarding these drugs and their disposition must be maintained in the ~~pharmacy~~ facility. The drug monograph and a signed patient consent form must be obtained and made available in accordance with state and federal guidelines.

(5) A sample drug policy must be established if samples are used.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-307, 37-7-308, MCA

NEW RULE VI (ARM 24.174.1104) INSTITUTIONAL PHARMACIST AND PHARMACIST-IN-CHARGE RESPONSIBILITY (1) through (1)(d) remain as proposed.

(e) a ~~mechanism~~ policy by which ~~changes in a patient's~~ an offer is made to convey the discharge medication regimen ~~are conveyed~~ to ~~that~~ a patient's ~~home pharmacy~~ pharmacies;

(f) through (s) remain as proposed.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-307, 37-7-308, MCA

NEW RULE VII (ARM 24.174.1121) STERILE PRODUCTS

(1) remains as proposed.

(2) An institutional pharmacy compounding sterile products must have an isolated area ~~restricted to entry by authorized personnel. That area must be~~ designed to avoid unnecessary traffic and airflow disturbances.

(3) An institutional pharmacy compounding sterile products must utilize an appropriate aseptic environmental control device such as a laminar flow biological safety cabinet capable of maintaining Class 100 conditions during normal activity, or have policies and procedures in place limiting the pharmacy's scope of sterile product preparation.

(4) An institution preparing cytotoxic drugs must have a vertical flow Class II biological safety cabinet. Cytotoxic drugs must be prepared in a vertical flow Class II biological safety cabinet. ~~Non-cytotoxic sterile pharmaceuticals must not be compounded in this cabinet.~~

(a) through (8) remain as proposed.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-307, 37-7-308, MCA

NEW RULE IX (ARM 24.174.411) PHARMACIST MEAL/REST BREAKS (1) remains as proposed.

(2) The time of ~~closure and re-opening~~ the meal/rest break will be conspicuously posted in clear view of patients approaching the prescription area ~~and will be consistently scheduled~~.

(3) through (9) remain as proposed.

(10) New hardcopy prescriptions may be accepted and processed by registered technicians in the pharmacist's absence. These prescriptions may not be dispensed until the pharmacist has performed ~~drug utilization~~ prospective drug review and completed the final check.

(11) and (12) remain as proposed.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

8. After consideration of the comments, the Board has repealed ARM 24.174.302, 24.174.810, 24.174.811, and 24.174.812 as proposed.

9. The following comments were received and appear with the Board's response.

Comment 1: Three commenters stated that ARM 24.174.301(2), defining a Class IV facility, is confusing, and that it appeared to propose licensure of Class IV pharmacies located at family planning clinics. The commenters stated that pursuant to 37-2-104, MCA, family planning clinics that

dispense only factory-prepackaged oral contraceptives may do so without a Class IV Facility license.

Response 1: The Board agrees with the comments and has deleted the proposed amendment. Class IV facility is defined elsewhere, and the present rules for Class IV facilities remain unchanged.

Comment 2: One commenter suggested that as long as the Board is revising the rules, it should be clear what family planning clinics need a Class IV license and which do not.

Response 2: The Board agrees with the comment. The topic of Class IV facilities and regulations pertaining to them will be addressed at a future time.

Comment 3: Two commenters raised the question of whether a Class 100 environment is required outside of a hood in the IV room.

Response 3: The Board concludes that a Class 100 environment is not required. Although a clean room is defined in, it was not the intent of the Board to require a hood to be located only in a technical clean room. The Board recommends that hood placement be carefully considered however, and that hoods be placed so as to avoid unnecessary traffic and airflow disturbances.

Comment 4: One commenter suggested that the definition of drug order in ARM 24.174.301(8) should be expanded to include electronic transmission, which is a future standard of practice.

Response 4: The Board agrees and has amended the definition accordingly.

Comment 5: Two commenters stated that the requirement of ARM 24.174.301(8), to have a verbal order signed by an authorized practitioner at a later date, should be deleted in order to avoid confusion between an inpatient drug order and an outpatient prescription.

Response 5: The Board agrees and the requirement has been deleted. The definition of drug order is intended to address patients within a facility, not outpatients in an ambulatory setting.

Comment 6: One comment was received suggesting that ARM 24.174.301(13) needed to be clarified by substituting the correct term of "outpatient center for surgical services" for the term "ambulatory surgical facility".

Response 6: The Board agrees and has amended the definition accordingly.

Comment 7: One comment suggested that the word "care" be added to clarify the meaning of "long term facility" in ARM 24.174.301(13).

Response 7: The Board agrees and has amended the definition accordingly.

Comment 8: One commenter suggested that ARM 24.174.301(14) should define floor stock as containing both prescription and non-prescription drugs. The commenter stated that floor stock is comprised of both.

Response 8: While over-the-counter drugs do not require a prescription by definition, their use within an institution requires the order of an authorized practitioner. No medication in an institutional setting can be given without a valid order. The Board concludes that the proposed definition is adequate.

Comment 9: One comment suggested that ARM 24.174.301(16) should be clarified by the addition of the words "for home infusion", citing that in some cases outpatients receive infusions mixed within the facility while maintaining outpatient status.

Response 9: The Board agrees and has amended the definition accordingly.

Comment 10: Two commenters stated that ARM 24.174.301(17) defining institutional pharmacy incorrectly inferred that federal pharmacies are subject to state licensure.

Response 10: The Board agrees and has amended the definition accordingly.

Comment 11: One comment asked whether the definition of "institutional pharmacy" in ARM 24.174.301(17) includes family planning clinics under contract with DPHHS.

Response 11: No, it does not. It is not the intent of the Board to include family planning clinics within this rule. The rules related to family planning clinics will be examined for clarification in the near future, as noted in Response 2 above.

Comment 12: One commenter stated that tests of written and spoken English should not be required for graduates from other English-speaking countries.

Response 12: The Board notes that this requirement is in line with the policies of the National Association of Boards of Pharmacy (NABP). Varying from NABP requirements would put Montana at risk of being denied reciprocal licensure status with other states. The Board also notes that NABP has recently recognized graduates of accredited Canadian colleges of

pharmacy. Those graduates will soon be able to sit directly for the NAPLEX licensing exam in Montana and other states without going through the Foreign Pharmacy Graduate Equivalency Exam, the test of English as a foreign language, and the test of spoken English.

Comment 13: One commenter questioned what are "appropriate" English language skills? The commenter stated "I have spoken to many who their second language is English. It is very hard to understand them & some barriers always exist. How will they be able to fulfill the counseling requirement when the patient is unable to understand the information given & unable to convey what information they don't understand?"

Response 13: The Board agrees with the commenter that the ability to speak, write and understand English is a critical component of pharmacy practice, and that lack of a pharmacist's ability to speak and understand English could place patients at risk due to ineffective counseling. The board has therefore clarified ARM 24.174.501(3) by requiring a successful interview before the board of pharmacy.

Comment 14: Two comments were received opposing the present 1:1 ratio, stating that a 1:1 ratio was unnecessarily restrictive and did not allow the provision of good pharmaceutical care.

Response 14: The Board did not propose any changes to ARM 24.174.711(1) through (4), and thus the Board believes it is inappropriate to make changes to a part of the rule that has not been properly noticed for public comment. The Board states that the purpose of additions (5) and (6) above is to facilitate tech ratio variance requests, enabling ratios of greater than 1:1 on a site-specific basis. The Board believes that the decision to increase the tech-to-pharmacist ratio in a specific location must be based on clinical advantages to the patient through the facilitation of good pharmacy practice. To that end, the Board has worked with representatives of the Montana Pharmacists Association and surveyed other states to obtain language to aid practitioners in making their ratio variance requests, and to aid the Board in accepting or rejecting those requests. A white paper has recently been approved by the Board that will further facilitate the processing of tech ratio variance requests.

Comment 15: One commenter proposed restricting the number of prescriptions filled per hour by each pharmacist to prevent pharmacist fatigue and protect patient safety.

Response 15: This topic was not included in the proposed rule change wording, and therefore the Board concludes it would be improper to address at this time. The Board notes that while the concept may be good, many states have found such requirements to be difficult to enforce. In addition, the

Board notes that the maximum rate at which individual pharmacists accurately fill prescriptions is highly variable.

Comment 16: Three commenters stated that pharmacists are fully capable of determining the number of technicians they can safely supervise, and therefore no mandatory maximum ratio should be necessary.

Response 16: The Board agrees with the comment, but notes that the final decision on ratio is often out of the pharmacist's hands, falling instead into the hands of the institution or corporation for whom the pharmacist practices. The Board states that in order to protect public health, a general technician ratio must be based on the characteristics of average practice settings, with the goal of facilitation of good pharmacy practice. The Board notes that a ratio variance request process is available on a case-by-case basis.

Comment 17: One comment suggested that clarifying in ARM 24.174.711 the mechanism by which approved technician utilization plans could be cancelled would be helpful as the subject is not adequately addressed.

Response 17: The Board agrees and has amended the rule accordingly.

Comment 18: Two commenters sought clarification whether ARM 24.174.1411 would make it necessary for a pharmacist to notify the police department, the Board of Pharmacy and the DEA "every time we're off by one on the controlled substance count."

Response 18: The Board notes that requirement of reporting the loss of controlled substances to the Board of Pharmacy and the DEA already exist in ARM 24.174.1411. The proposed requirement of ARM 24.174.1411(4) to report loss of controlled substances to law enforcement as well is in addition to those requirements. No threshold defining the minimum amount of loss for reporting is provided by statute, Board rule, or DEA regulation. However, the Board suggests that practitioners ought to err on the side of caution.

Comment 19: One commenter noted that it may not always be possible to obtain a police report, causing compliance with the requirement to be difficult.

Response 19: The Board agrees, and has amended the rule to delete the requirement to forward a copy of the police report to the Board within 30 days of the filing of the report.

Comment 20: Four commenters stated that NEW RULE I requirement of dual licensure for institutional pharmacies providing outpatient services would increase costs while not

providing for a substantial increase in public health and safety.

Response 20: The Board has concluded that the comments are well taken. The Board is not adopting NEW RULE I.

Comment 21: Eleven commenters stated that NEW RULE II would require 24-hour pharmacist coverage, which would be difficult and prohibitively expensive for many rural hospitals. The commenters expressed concern that NEW RULE II would require rural hospitals to contract with a pharmacy that is open or is willing to be available 24 hours per day.

Response 21: The Board does not intend to cause a hardship upon rural hospitals. However the Board believes that emergency pharmacy service is the existing minimum standard of care. Emergency pharmacy service is presently required for Class I and Class II hospitals in the State of Montana. NEW RULE II has been amended by the addition of the words "a mechanism for" to further clarify that the rule is intended to assure that emergency services are available at all times as described in the policies and procedures adopted by a hospital, not that the pharmacist must personally cover 24 hours per day. The Board respectfully suggests that institutions without 24 hour pharmacy service address this situation, as most institutions already have, through the use of night cabinets and emergency room stock. The Board believes that only on rare occasions, when a patient's medical circumstances made it necessary would the institution's pharmacist or a pharmacist in another town need to be contacted for clinical advice.

Comment 22: One commenter sought clarification of the term "available by phone", asking if phone availability needed to be immediate.

Response 22: The Board acknowledges that immediate availability might not always be necessary or possible, and states that pharmacy consultation should be available within a reasonable period of time.

Comment 23: One commenter suggested that NEW RULE III should be modified to clearly state that the pharmacist available does not have to live in the same town or be immediately available.

Response 23: The Board has modified NEW RULE III(1) by the addition of the words "A mechanism for providers and nursing to obtain pharmacy consultation must be available at all times..." to further clarify that NEW RULE III is intended to assure that emergency services are available at all times as described in the policies and procedures adopted by each institution, not that the pharmacist must personally cover 24 hours per day.

Comment 24: One commenter stated that the Board is usurping medical staff's discretion to organize and deliver health care.

Response 24: The Board does not intend to usurp medical staff discretion. However, the Board is required by 37-7-102, MCA, to regulate the practice of pharmacy and protect public health and safety. The Board concludes that this rule constitutes a reasonable regulation of the practice of pharmacy and that it is necessary to protect the public health and safety.

Comment 25: Ten commenters stated that NEW RULE III(4), requiring that a verification audit be conducted within 24 hours of removing drugs from the night cabinet, would cause difficulty and additional expense for institutions with no weekend pharmacy service.

Response 25: The Board does not intend to cause hardship upon institutions without weekend pharmacy service. However, the Board concludes that the risk of patient harm increases with each day that a dosing or medication error is not caught and corrected. The Board has compromised by changing the 24-hour period to a 48-hour period in which to perform a verification audit. The Board believes that a time lapse of more than 48 hours could potentially jeopardize patient health and safety. The board points out that electronic mechanisms are available and can be used for verification audits if needed. Mention of this option was retained for clarity.

Comment 26: Four commenters stated that final HIPAA (Health Insurance Portability and Accountability Act) requirements will have to be considered before the faxing of orders is undertaken.

Response 26: The board agrees that final HIPAA requirements must be considered and complied with when faxing of orders is contemplated.

Comment 27: Two comments on NEW RULE III(5) stated that the nurse accessing the pharmacy should not have to be limited to nurses in a supervisory role, as supervisors are often busy with emergencies.

Response 27: The Board agrees with the comment and has amended the rule accordingly.

Comment 28: Two commenters suggested that a licensed practical nurse could be used in the context of NEW RULE III(5) rather than a registered nurse.

Response 28: The Board agrees with the comment and has amended the rule accordingly.

Comment 29: One commenter suggested that NEW RULE III(5)(a)

should be clarified to specify that the recording form used by an authorized nurse when removing drugs from the pharmacy be left in the pharmacy to avoid confusion.

Response 29: The Board agrees with the comment and has amended the rule accordingly.

Comment 30: Two commenters suggested that the term "NDC number" should be added to NEW RULE III(5)(a)(iii) to facilitate drug identification, which would be useful to verify drug identity even if the pharmacist was in a neighboring town.

Response 30: The Board agrees with the comment and has amended the rule accordingly.

Comment 31: Three comments regarding NEW RULE III(5)(b) stated that requiring the form to be sequestered in the pharmacy with the container from which the drug was removed and a copy of the original drug order could possibly increase expense and is impractical. A copy of the original drug order for purposes of verification can be found in the patient's chart.

Response 31: The Board agrees with the comment and has amended the rule accordingly by deleting subsection (5)(b). The Board added "documentation of pharmacy review" in NEW RULE III(5)(a)(vi) to replace the requirement for pharmacy review of orders deleted in (5)(b).

Comment 32: Seven commenters stated that the requirement for prospective drug review in NEW RULE III(6) was an impractical requirement, that the pharmacist at home does not have the patient profiles necessary to make good clinical decisions, and that a requirement for prospective review would be contrary to providing appropriate emergency service in a timely manner.

Response 32: The Board agrees with the comment and has amended the rule accordingly.

Comment 33: Two commenters questioned whether the "designee" in NEW RULE III(4) must be a registered pharmacist.

Response 33: The Board states that one of the most important purposes of a verification audit is to determine the safety and appropriateness of a medication order for a specific patient and to verify that no errors have been made. Policies and procedures can designate certified pharmacy technicians to check and replace medications used under the supervision of a pharmacist. However the Board concludes that a registered pharmacist must be the one to review and evaluate the medication order for safety and appropriateness.

Comment 34: One commenter asked if automated dispensing machines should be treated the same as night cabinets.

Response 34: Automated dispensing machines are not presently addressed and regulations to clarify their use will be considered in the near future.

Comment 35: One commenter suggested that the Board may need to establish some rules for what items need to be monitored (reports, high risk drugs, mixing information, discrepancies, narcotics, etc.) with regard to automated dispensing machines.

Response 35: The Board states that the comment is well taken. The Board will consider the topic in the near future.

Comment 36: Three commenters stated that the requirement to notify the pharmacist of any entry into an emergency kit within 24 hours may not always be necessary and that emergency kits are often stocked with multiple doses of a drug within an institution. Unnecessary requirements could cause difficulty and unnecessary expense.

Response 36: The Board has concluded that the comments are well taken, and has changed NEW RULE IV(3) to require a policy delineating how restocking and resealing will be accomplished within a reasonable period of time.

Comment 37: The Montana Nurses' Association suggested that the words "staff physician" in NEW RULE IV(1)(b) should be changed to "designated practitioner" to lend flexibility and address a wider range of practice situations.

Response 37: The Board agrees with the comment and has amended the rule accordingly.

Comment 38: One commenter suggested that the title of NEW RULE V be clarified by adding "in an institutional facility" to avoid confusion with community pharmacies.

Response 38: The Board agrees with the comment and has amended the rule accordingly.

Comment 39: Seven commenters stated that the requirement for prospective drug review in NEW RULE (V)(1) could be impractical and hinder emergency care.

Response 39: The Board agrees with the comment and has amended the rule accordingly.

Comment 40: One commenter suggested that the requirement for documentation should be added to NEW RULE V(1) for verification of drug review.

Response 40: The Board agrees with the comment and has amended the rule accordingly.

Comment 41: One commenter questioned the necessity of pharmacist supervision regarding stocking of automated dispensing machines in NEW RULE V(2).

Response 41: The Board believes that pharmacist supervision does not necessarily have to be direct in this instance, but a pharmacist check must occur. A pilot tech-check-tech project has successfully been completed in one Montana institution, leading the way for approval of future pilot projects and upcoming changes in rule. Clarifying rules for automated dispensing machines will be proposed by the Board in the near future.

Comment 42: Three commenters stated that the NEW RULE V(3) requirement for pharmacist identification of drugs, herbals and alternative food supplements brought into a facility by a patient would be expensive, impractical and even impossible in some cases, and could cause unacceptable delay.

Response 42: The Board concludes that, due to the possibility of adverse reactions and serious if not fatal drug interactions, patient safety cannot be ensured if unidentified medications are given. Therefore, medications that cannot be properly identified should not be administered to a patient.

Comment 43: Two commenters suggested that the wording of NEW RULE V(3) be changed to allow the use of home medications without identification and inspection by a pharmacist if the medication is sent directly from another pharmacy to the institution.

Response 43: The Board believes that this requirement has been satisfied when a policy is adopted within an institution stating that medications sent directly from a pharmacy to the facility for a specific patient are considered to have been checked by a pharmacist.

Comment 44: One commenter suggested that maintenance of investigational drug information in NEW RULE (V)(4) be changed to be located within the facility, rather than the pharmacy, for practicality and greater flexibility.

Response 44: The Board agrees with the comment and has amended the rule accordingly.

Comment 45: One commenter on NEW RULE V(4) suggested that the term "state guidelines" be added to "federal guidelines" for completeness and accuracy.

Response 45: The Board agrees with the comment and has amended the rule accordingly.

Comment 46: One commenter questioned if the NEW RULE V could be supplemented to address procedures for handling investigational drugs approved by another investigational review board that have been brought into a facility by a patient for personal use.

Response 46: The Board believes that policies and procedures can be written within the individual institution to address the handling of investigational drugs in this instance.

Comment 47: One commenter suggested that the handling of prescription drug samples should have been mentioned in NEW RULE V.

Response 47: The Board agrees with the comment and has amended the rule accordingly.

Comment 48: Four commenters testified in support of NEW RULE VI(1)(e), stating that continuity of care is an important goal and that communication between sites must be improved for the sake of patient safety.

Response 48: The Board acknowledges the comments.

Comment 49: One commenter asked for clarification of the word "mechanism" in NEW RULE VI(1)(e).

Response 49: The Board agrees that the word "mechanism" is unclear. "Mechanism" is changed to "policy" for clarity.

Comment 50: Thirteen commenters stated that the requirements of NEW RULE VI(1)(e) were difficult, impractical, potentially costly and "beyond our scope of practice and ability".

Response 50: The Board has no desire to place practitioners in a difficult, impractical and costly situation. The Board has amended the language to require only an offer to convey the medication regimen upon discharge to the pharmacy or pharmacies of the patient's choice. However, the Board maintains that a pharmacist's responsibility doesn't end at discharge. Physicians and other practitioners who routinely send discharge summaries or letters to other practitioners also caring for the patient have set good precedent in this area.

Comment 51: One commenter stated that the continuity of care required by NEW RULE VI(1)(e) is a worthy goal, but that few if any non-HMO organizations are currently doing this nationwide. The commenter concluded by stating "This certainly is not a minimum standard."

Response 51: The Board agrees with the commenter, but again maintains that a pharmacist's responsibility doesn't end at discharge. An offer to convey the medication regimen upon

discharge could have a critical impact on patient outcomes.

Comment 52: Three commenters questioned whether the requirement of NEW RULE VI(1)(e) would violate final HIPAA regulations.

Response 52: The Board agrees that the commenters raise a valid point. The amended language, requiring only an offer to convey, should ease some privacy concerns and concern about compliance with HIPAA as any action would be requested and/or approved by the patient. The Board suggests that a photocopy or copies of only the medication portion of the discharge summary, or a photocopy of the final medication administration record (with diagnosis and other sensitive information omitted) could be sent along with the patient to give to their pharmacist, or sent or faxed to the pharmacies the patient requests at minimal expense and effort. Policies can be established to address the way in which this can most easily be accomplished within each individual institution. This intervention could minimize the chance of unexpected drug interactions or therapeutic duplication by alerting other pharmacies to the fact that medication changes have been made, and that consultation with the patient's physician or other practitioner could be in order.

Comment 53: One commenter stated that the provisions of NEW RULE VI(1)(e) would violate patient privacy, stating that "psychotic, sex, drugs, etc. are gossiped about" by pharmacists and pharmacy technicians, especially in small towns.

Response 53: The Board states that the offer to notify requires patient consent, making it voluntary for the patient to accept or refuse. Pharmacists and pharmacy technicians are professionals and the Board expects and requires them to act as such and maintain confidentiality concerning patient information.

Comment 54: One commenter stated that the requirements of NEW RULE VI(1)(e) "would lead to a restraint of trade issue" in which "the pharmacists want to keep all of a patient’s business".

Response 54: The Board notes that the language of NEW RULE VI (1)(e) has been amended to require only an offer to convey discharge information. The Board does not see how restraint of trade would be an issue in this case.

Comment 55: Two commenters stated that NEW RULE VI(1)(e) ignores the fact that many patients patronize multiple pharmacies, and that it would be difficult and time consuming to fax information to multiple pharmacies.

Response 55: The Board concurs that some patients patronize

multiple pharmacies, and changed the term "home pharmacy" to "pharmacies" to address this point. The Board emphasizes that routinely patronizing more than one pharmacy is a potentially dangerous practice, as no one pharmacist has an accurate patient profile to consult. The Board believes a pharmacist who recognizes that a patient patronizes multiple pharmacies is presented with a unique and important opportunity for patient education.

Comment 56: Three commenters stated that NEW RULE VII(2) appears to require a clean room in addition to an appropriate biological safety cabinet, and that such a requirement would be expensive and difficult if not impossible for small rural hospitals.

Response 56: It is not the Board's intent to require a separate clean room. The Board has changed the wording of NEW RULE VII(2) from "restricted to entry by authorized personnel" to "isolated" for clarification.

Comment 57: Four commenters stated that the requirement of NEW RULE VII(3) that all sterile product preparation be done in a laminar flow hood or other aseptic environmental control device was potentially too costly for small rural hospitals.

Response 57: It is not the Board's desire to impose hardship upon rural hospitals. The board has changed the language of NEW RULE VII(3) to require "either an appropriate biological safety cabinet for sterile product admixture or policies that limit sterile product preparation". In making this decision, the board consulted several studies referenced by the American Society of Health Systems Pharmacists. For the protection of the patient, parenteral admixtures should ideally be prepared in some sort of aseptic environmental control device. Many small facilities mix only partial fills with a short hang time and large volume base solutions with electrolytes and/or multivitamins. These do not present the high risk for bacterial growth that some admixtures do, and could be safely mixed in merely a clean isolated area with careful aseptic technique. However, admixtures offering a prime environment for bacterial growth such as total parenteral nutrition and lipids, and sterile products for high-risk patients (immunocompromised, neonates, etc.), should be mixed in an aseptic environmental control device. The Board believes that in the absence of a hood, institutional policies can be written to delineate high-risk admixtures from simpler ones and limit the types of admixtures that can be prepared. The Board feels that this change will not unnecessarily put patients at risk.

Comment 58: Ten commenters stated that NEW RULE VII(4) requiring that non-cytotoxic drugs not be prepared in the same vertical flow Class II biological safety cabinet as cytotoxic drugs was unworkable for small facilities. Commenters cited

the possibility of "substantial new costs" and "unreasonable limits on current practice" which would "threaten to terminate chemotherapy services in some communities."

Response 58: The Board has no desire to impose hardship upon facilities or entire communities. After weighing the comments received, the Board has dropped the requirement that non-cytotoxic products should not be mixed separately in the same cabinet as cytotoxic drugs. The Board has a degree of concern about this change due to published studies on chemotherapy residue following cleaning of surfaces, but for now will rely on good cleaning technique of vertical flow hoods to minimize the risk of contamination, as well as good professional judgment.

Comment 59: One commenter on NEW RULE VIII stated, "Medication return from long term care facilities should be more liberalized to reduce the cost of care to its clients/state/insurance company/taxpayers. These meds are dispensed in unit dose containers and should be able to be reused on any patient without the amount of record keeping."

Response 59: The Board concludes that proper records are necessary to guarantee potency and protect patient safety, and to ensure compliance in the event of a drug lot recall.

Comment 60: One commenter questioned the meaning of the term "provisional pharmacy".

Response 60: The Board notes that the term "provisional community pharmacy" is defined in Chapter 362, Laws of 2001 (Senate Bill 288, codified as Title 37, chapter 7, part 14, MCA). The Board uses the term "provisional pharmacy" in this context as meaning the same as "provisional community pharmacy".

Comment 61: One commenter noted that "the time of closure and re-opening" in NEW RULE IX(2) could be confused with the regular opening and closing hours of the pharmacy.

Response 61: The Board agrees with the comment. The Board has amended NEW RULE IX(2) to read "the time of the meal/rest break" for increased clarity and accuracy.

Comment 62: Two commenters suggested that the term "drug utilization review" in NEW RULE IX(10) should be replaced by the term "prospective drug review" for accuracy.

Response 62: The Board agrees with the comment and has amended the rule accordingly.

Comment 63: Six commenters testified that the requirement of NEW RULE IX(2) to consistently schedule meal/rest breaks would potentially be unworkable and counterproductive. One commenter

stated "If the Board intends the term 'consistently scheduled breaks' to mean that breaks be taken at or about the same time each day, then we believe that this requirement would decrease pharmacists' professional satisfaction by removing pharmacists' judgment in determining the optimal time for a break." Other comments cited that the requirement would have "the adverse effect of raising pharmacists' stress."

Response 63: The Board agrees with the comments, and has deleted the requirement that breaks be consistently scheduled. The Board agrees that workload is not always a predictable factor, and that variations will occur. The Board hopes that the break will be somewhat predictable for the sake of patients, but agrees that establishing an absolute time in advance is not always practical.

Comment 64: One commenter stated, "Research on pharmacy errors has shown that the causes are more complicated than workload."

Response 64: The Board agrees the commenter makes a valid point, but notes that workload can be a major contributing factor.

Comment 65: Three commenters testified in support of a mandatory meal/rest break. One stated, "I would like to say thank you very much for proposing this rule. A meal break is a great common sense humanitarian thing for the practice. I am wholeheartedly behind it."

Response 65: The Board acknowledges the comments.

Comment 66: One commenter stated, "the board is . . . beginning to move away from providing the standards under which an institution can be licensed and moving toward facility management standards. Standards for licensure surely don't require the board to govern daily work rules. Federal and state statutes related to employment adequately protect worker rights."

Response 66: The Board notes, as do the Boards of Pharmacy in many jurisdictions, that a meal/rest break is not so much about protecting worker rights as protecting patient rights to health and safety. The Board concludes that a fatigued pharmacist may not make the best clinical decisions.

Comment 67: Two commenters questioned whether the meal/rest break requirement would force pharmacists in an institutional/long-term care setting to remain in the pharmacy rather than engage in consulting and clinical roles on the floor. One commenter voiced concern that the role of institutional pharmacists in a clinical/consultant role could be reduced to "a dispensing role only."

Response 67: The Board concludes that the new institutional practice regulations spell out the ability of the pharmacist in charge to define these circumstances in policy and procedure. NEW RULE V, Drug Distribution and Control in an Institutional Facility, provides that "The pharmacist-in-charge shall establish written policies and procedures for the safe and efficient distribution of drugs and provision of pharmaceutical care, including the mechanism by which drug review will be accomplished and documented. A current copy of such procedures must be on hand for inspection by the board of pharmacy." The Board recognizes that institutional pharmacists often perform clinical functions outside the pharmacy and no attempt has been made to change that. NEW RULE IX applies to a daily meal/rest break only.

Comment 68: Five commenters stated opposition to any mandatory meal/rest break, stating that the matter should be up to the professional judgment of the pharmacist, and that a forced break could add to a pharmacist’s stress.

Response 68: The Board concludes that the language proposed, "up to 30 minutes per shift", provides maximum flexibility. The Board agrees that the duration of a break should remain a matter of professional judgment. However, the Board believes that a break must be taken even on the busiest of days to ensure patient safety.

Comment 69: Two commenters supported a mandatory break of at least 30 minutes daily.

Response 69: The Board concludes that the language proposed, "up to 30 minutes per shift", provides maximum flexibility, and that language was maintained in light of all comments received.

BOARD OF PHARMACY
ALBERT A. FISHER, R.Ph.,
PRESIDENT

By: /s/ KEVIN BRAUN
Kevin Braun
Rule Reviewer

By: /s/ WENDY J. KEATING
Wendy J. Keating, Commissioner
DEPARTMENT OF LABOR & INDUSTRY

Certified to the Secretary of State, December 16, 2002.